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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,291	11/30/1999	LIEPING CHEN	07039-187001	8838

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EXAMINER

SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/13/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/451,291

Applicant(s)

CHEN, LIEPING

Examiner

Jehanne E Souaya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,11-13,36,37 and 46-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,11-13,36,37 and 46-51 is/are rejected.
- 7) ☐ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4-5, 11-13, 36, 37, and 46-51 are pending in the instant application. The claims are newly rejected over a reference which has recently become available. Prosecution is reopened. This action is NON-FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4, 11-13, 36, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Freeman et al (US publication 2002/0102651, effective 102(e) date: 8/23/1999).

Freeman et al teach and claim the polypeptide sequence of SEQ ID NO 4, which is encoded by the polynucleotide of SEQ ID NO 3 (see sequence listing, claims). SEQ ID NOS 3 and 4 of Freeman et al are identical to SEQ ID NOS 2 and 1, respectively of the instant application.

With regard to instantly pending claim 1, Freeman et al teaches SEQ ID NO 3 of Freeman et al, which encodes SEQ ID NO 4 of Freeman et al as well as SEQ ID NO 1 of the instant invention (see claim 2 of Freeman). Freeman teaches that the polypeptide of SEQ ID NO 4 of Freeman has the ability to costimulate T cells (see example 4, p. 35 of Freeman et al). With

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regard to instantly pending claim 2, Freeman et al teaches SEQ ID NO 3 (see sequence listing, claim 1 of Freeman et al) which is identical to SEQ ID NO 2 of the instant invention. With regard to claims 11-13, 36, and 37, Freeman et al teach expression vectors and cells expressing the polypeptide of SEQ ID NO 4 of Freeman et al (p. 36, col. 2 and claims 8-11 of Freeman et al).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 46-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al.

Freeman et al teach B7-4 polypeptides such as the polypeptide sequence of SEQ ID NO 4, which is encoded by the polynucleotide of SEQ ID NO 3 (see sequence listing, claims). SEQ ID NOS 3 and 4 of Freeman et al are identical to SEQ ID NOS 2 and 1, respectively of the instant application.

Freeman et al do not specifically teach an isolated DNA comprising a nucleic acid encoding a polypeptide consisting of instantly pending SEQ ID NO 1 but lacking amino acids 1-22, however Freeman et al do teach constructing vectors for inducible expression of B7-4 protein in eukaryotic cells, such as yeast (p 17, col. 2, end of para 0156 and para 1059). It is further noted that amino acids 1-22 of instantly claimed SEQ ID NO 1 is taught by the instant specification to be a signal peptide. Furthermore, methods of cloning and expressing proteins

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with that contain a signal peptide in foreign host cells such as yeast, were known in the art at the time of the invention. For example, Romanos et al ("Expression of cloned genes in yeast" from Cloning 2: A practical Approach, IRL press, 1995, chapter 5, pp 133-148) teach proteins can be expressed in *S. cerevisiae* wherein the signal peptide of the protein is removed and placed in a secretion vector which expresses a fusion protein (yeast signal peptide joined to the foreign protein lacking it's own signal peptide) (see p. 134-135). Romanos et al teach that such can be useful, for instance, to express foreign proteins secreted to a high level which may only need minimal purification. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct a DNA molecule, for example for expression in yeast, as taught by Freeman et al, wherein the DNA molecule comprised a vector which contained a signal peptide specific to the foreign host and a nucleic acid encoding SEQ ID NO 4 of Freeman et al (SEQ ID NO 1 of the instantly claimed invention) minus the signal peptide of SEQ ID NO 4 as Romanos et al teach that such is necessary when expressing proteins with signal peptides in foreign hosts. Although Freeman et al do not teach a specific peptide signal sequence, and instead teach that SEQ ID NO 4 of Freeman et al contains a signal peptide at "about amino acids 1-18" (see p. 11, col. 1, para 0109), it would have further been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct a number of different vectors comprising different fragments of SEQ ID NO 4 to determine the construct minus the complete signal sequence of SEQ ID NO 4 as Freeman et al only teach an approximate range of nucleic acids. Such constructs would include a nucleic acid encoding SEQ ID NO 4 of Freeman et al minus the first 22 amino acids as the ordinary artisan would have realized that without a specific range, a number of different constructs would have to be made to

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determine the exact signal sequence, such as constructs +/- 4-5 amino acids on either side of the range, and arrive at the construct and method of making the polypeptide encoded by the construct of the instantly claimed invention.

Conclusion

6. Claim 5 is allowable over the cited prior art. Freeman et al teach the nucleic acid of SEQ ID NO 10 (murine) which encodes SEQ ID NO 11, which are identical to SEQ ID NOS 4 and 3 of the instant application, respectively. However, these sequences receive priority to 8/23/2000, not to 8/23/1999, and are therefore not prior art under 35 USC 102(e). Claim 5 is objected to for being dependent on a rejected claim.

7. **Applicant Note:** A declaration under 37 CFR 1.131 or 1.132 would not be sufficient to overcome the rejection. See 37 CFR 1.608(b).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Patent examiner
Art Unit 1634

Jehanne Souaya
5/7/03